

not raise new issues and should be entered for purposes of appeal in accordance with 37 C.F.R. § 1.116(a) and MPEP 714.12 and 714.13.

Attached hereto as Exhibit A is the Declaration of David K. Swanson under 37 C.F.R. § 1.132 (the "Swanson Declaration"). The Swanson Declaration is discussed below where applicable.

II. BRIEF DESCRIPTION OF THE ILLUSTRATED EMBODIMENTS

The present invention, as defined by claims 1-20, 28, 30 and 32, is directed generally to a system for ablating tissue. As shown by way of example in FIG. 59, the system 298 includes a controller 300 and probe 180 that may be inserted into the body. The probe includes an ablation element 176(1) which, in the exemplary embodiment, consists of a plurality of conductive regions E1 to E7 that form an energy emitting region 192. The exemplary controller 300 can be used to selectively switch the operation of the electrodes between unipolar and bipolar ablation modes. The controller 300 can also be used to selectively energize some or all of the respective conductive regions E1 to E7 to form a variety of lesion patterns and lengths. [See the specification from, for example, page 53, line 31 to page 58, line 17 and FIGS. 59-66.] Some of these lesion patterns are formed when two conductive regions are separated by a non-conductive region. [See FIGS. 33-35.]

III. REJECTION OF CLAIMS 1-20

A. Rejection

Claims 1-20 have been rejected under 35 U.S.C. § 103 as being unpatentable over the combined teachings of the Houser patent and Mackey article. The rejection under 35 U.S.C. § 103 is respectfully traversed. Reconsideration thereof is respectfully requested.

B. Independent claims 1 and 12

Independent claim 1 calls for a combination of element including, *inter alia*, control means ... **for electronically altering energy transmission from the [energy emitting] region between transmission as a zone of uniform polarity and transmission as zones of alternating polarity in response to the prescribed input command**. Independent claim 12 calls for a combination of elements including, *inter alia*, control means ... **for selectively electronically altering the energy transmitting characteristics of the region to block transmission from portion of the region while allowing transmission from another portion of the region**.

As discussed in the amendment filed September 4, 1997, the combined teachings of the Houser patent and Mackey article fail to teach or suggest such combinations. In particular, the cited references do not teach or suggest the respective functions defined by the means-plus-function portions of independent claims 1 and 12, nor do they teach or suggest means identical to, or the equivalent of, the structure material, or acts described in the present specification. The arguments from the September 4, 1997 amendment concerning independent claims 1 and 12 are incorporated herein by reference. To the extent that the rejection is based solely on the Houser/Mackey combination, applicant respectfully submits that the rejection under Section 103 is improper and must be withdrawn.

In response to applicant's arguments, the Examiner refers to the teachings of the newly cited Imran patent (discussed below) "as evidence of the knowledge in the prior art." Thus, it appears that the rejection of claims 1-20 is now based on the combined teachings of the Houser, Mackey and Imran references, which is a new ground of rejection. [Note that the prior rejection was not based on Houser, Mackey and other knowledge in the prior art.] As claims 1-11 and 13-15 were not amended in the September 4, 1997 amendment, applicant respectfully submits that the new ground of rejection precludes a final rejection of these claims. [See MPEP § 706.07(a).] To the

extent that the rejection is now based on Houser/Mackey/Imran combination, applicant respectfully submits that a supplemental, non-final Office Action should be issued which clearly indicates that this is the case.

This issues discussed in the preceding paragraph notwithstanding, the Imran patent cannot remedy the deficiencies in the Houser/Mackey combination because the Imran patent fails to provide an enabling disclosure of power switching in an ablation catheter environment. In particular, the Imran patent discloses the use of a multiplexer chip 86 (or chips 86a-c) located within the catheter probe 22. Applicant respectfully submits that, at the time the present invention was made, multiplexer chips both small enough to fit within a catheter probe and capable of switching the high current, high voltage power necessary for tissue ablation simply did not exist. [Swanson Dec. at ¶¶ 7-10]. Such chips do not even exist today. [Swanson Dec. at ¶ 11]. Thus, the device disclosed in the Imran patent is not capable of operating in the manner described in the patent.

As a non-enabled reference will not suffice as prior art, *In re Donohue*, 226 USPQ 619, 621 (Fed. Cir. 1985), applicant respectfully submits that the proposed Houser/Mackey/Imran combination fails to establish a *prima facie* case of obviousness. To the extent that the rejection under Section 103 is based on this combination, applicant respectfully submits that the rejection is improper and must be withdrawn.

C. Dependent claims 2, 13 and 15

Claim 2 calls for a combination of elements including, *inter alia*, control means that electronically varies the length of the region where emission occurs. Claims 13 and 15 call for respective combinations of elements including, *inter alia*, control means that electronically varies the length of the region where transmission is either blocked or allowed. The Office Action fails to point to any teachings in the cited references that show that such combinations would have been obvious and applicant respectfully submits that they do not. In particular, the Mackey reference merely discusses the

purported superiority of multipolar RF energy delivery and the Imran patent, as discussed in detail below in Section IV, merely states that power may be selectively applied to different electrode pairs.

Accordingly, for reasons in addition to those discussed above with respect to independent claims 1 and 12, applicant respectfully submits that the Houser and Mackey (and Imran) references fail to teach or suggest the combination of elements recited in claims 2, 13 and 15, whether viewed alone or in combination, and that the rejection thereof under 35 U.S.C. § 103 must be withdrawn.

D. Dependent claim 6 and 18

Claims 6 and 18 call for respective combinations of elements including, *inter alia*, energy transmitting material helically wrapped about and along the axis of the guide body. The cited references clearly fail to teach or suggest such combinations. Accordingly, for reasons in addition to those discussed above with respect to independent claims 1 and 12, applicant respectfully submits that the Houser and Mackey (and Imran) references fail to teach or suggest the combination of elements recited in claims 6 and 18, whether viewed alone or in combination, and that the rejection thereof under 35 U.S.C. § 103 must be withdrawn.

E. Dependent claim 14

Claim 14 calls for a combination of elements including, *inter alia*, control means that electronically alters the energy transmitting characteristics of the region to allow transmission from spaced apart first and second portions of the region while blocking transmission from a third portion of the region located between the first and second portions. The Office Action also fails to point to any teachings in the cited references that show that this combination would have been obvious. Applicant respectfully submits that they do not. The Mackey reference merely discusses the purported

superiority of multipolar RF energy delivery and, as discussed below in Section IV, the newly cited Imran patent merely discloses switching between different electrode pairs. Thus, Imran fails to provide any teachings which would remedy this deficiency in the Houser/Mackey combination.

IV. REJECTION OF CLAIMS 28-32

A. Rejections

Claims 28, 29 and 32 have been rejected under 35 U.S.C. § 102 as being anticipated by the Imran '151 patent and claims 30 and 31 have been rejected under 35 U.S.C. § 103 as being unpatentable over the Imran '151 patent. Applicant respectfully submits that the rejection under Section 102 is moot in view of the amendment above.¹ The rejection under Section 103 is respectfully traversed with respect to the claims as amended above. Reconsideration thereof is respectfully requested.

B. Discussion

Independent claim 28 calls for a combination of elements including, *inter alia*, a guide element for introduction into a body, a plurality of longitudinally spaced electrodes on the guide element, and a controller operably connected to the plurality of electrodes and to a source of tissue ablating energy ... the controller including switching means for selectively disconnecting at least one of the electrodes within the plurality of longitudinally spaced electrodes from the source of tissue ablating energy in response

¹ Applicant respectfully submits that the failure to reject claim 31 under Section 102 is a tacit admission that the cited reference fails to disclose the subject matter recited therein. As independent claim 28 has been amended to include the subject matter originally claimed in claim 31, which was rejected under Section 103, applicant respectfully submits that the rejection under 102 has been rendered moot and that the only rejection at issue is the rejection under Section 103.

to a first predetermined input command ***such that two electrodes are critically connected to the source of tissue ablating energy and the at least one disconnected electrode is between the two connected electrodes.*** The Imran patent fails to teach or suggest such a combination.

The Imran patent discloses a catheter which includes a plurality of electrode sets 66 that consist of electrodes 67 and 68. The Imran patent also discusses a computer and multiplexer arrangement which is used to supply power to a selected electrode pair. As discussed in detail above, the Imran patent does not provide an enabling disclosure with respect to ablation level power switching. For this reason alone, the rejection under Section 103 is improper and must be withdrawn. Additionally, and in contrast to the present invention, the Imran patent also fails to even remotely suggest that the computer and multiplexer arrangement may be used to supply ablating energy to two electrodes with a disconnected electrode therebetween.

The Office Action admits that such a combination is not taught by the Imran patent. Nevertheless, the Office Action states that the claimed combination would have been obvious because the claimed electrode configuration is "not critical" and because "if the claimed configurations were required they could be employed." Applicant respectfully submits that the conclusion of obviousness is improper for at least two reasons.

First, Section 103 does not include a criticality requirement. The proper inquiry is simply whether or not the prior art suggested applicant's claimed invention at the time the invention was made. Here, the answer is no. Second, as the Federal Circuit has stated on more than one occasion, the mere fact that the prior art could be modified does not make the modification obvious unless the prior art suggested the desirability of the modification. See, e.g., *In re Laskowski*, 10 USPQ2d 1397 (1989). Here, there is no such suggestion. Nothing in the Imran patent even remotely suggests that ablating energy may be supplied to two electrodes while an electrode therebetween is disconnected from the energy. Additionally, to the extent that the conclusory statements in the Office Action indicate that the Examiner has taken "judicial notice" with respect to knowledge generally

available in the catheter control device art, applicant hereby requests that the Examiner provide an affidavit in accordance with MPEP § 706.02(a) and 37 C.F.R. § 1.107(b) to that effect. The affidavit should set forth the facts upon which the Examiner's conclusions regarding the knowledge available in the art are based. Otherwise, applicant respectfully requests that the Examiner provide a prior art reference which shows that the claimed invention would have been obvious.

As the cited reference fails to teach or suggest the combination of elements recited in independent claim 28, applicant respectfully submits that the rejection under 35 U.S.C. § 103 is improper and must be withdrawn.

V. CLOSING REMARKS

In view of the foregoing, it is respectfully submitted that the claims in the application patentably distinguish over the cited and applied references and are in condition for allowance. Reexamination and reconsideration of the application, as amended, are respectfully requested. Allowance of the claims at an early date is courteously solicited.

If for any reason the Examiner finds the application other than in condition for allowance, the Examiner is respectfully requested to call Applicant's undersigned representative at (310) 788-5070 to discuss the steps necessary for placing the application in condition for allowance.

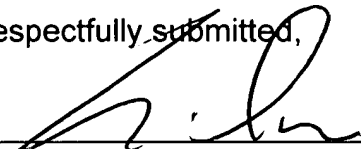
The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 16-2230. Should such

additional fees be associated with an extension of time, applicant respectfully requests that this paper be considered a petition therefore.

3/2/98
Date

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Respectfully submitted,



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